PHOENIX SCIENTIFIC, INC.

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816 364-3777 • Fax 816 364-3778

Suitability Petition

February 7, 2000

Dockets Management Branch
HFA-305, Room 123
Food and Drug Administration
Park Building
12420 Parklawn Dr.
Rockville, MD 20857

Dear Sir or Madam:

Enclosed is a Suitability Petition submitted in accord with FFDCA Section 512 (n) (3) on behalf of Phoenix Scientific, Inc., St. Joseph, MO 64503.

The Petition concerns a change in the physical form of the drug product in a generic Phenylbutazone Powder from the approved product, Phenylbutazone Tablets, USP 1 gram for oral use in horses, approved under NADA 91-818, for Phoenix Scientific Inc. The requested change is from a compressed tablet for the approved to a granulated powder for the generic.

If there are any questions concerning this petition, or when you have completed your review, please call me at (816) 364-3777.

Sincerely:
Phoenix Scientific, Inc.

Robert D. Gunderson
Vice President, Regulatory Affairs

00P-0596

CP1

3915 S. 48th St. Terrace • St. Joseph, MO 64503
P.O. Box 8039 (64508)

PHOENIX SCIENTIFIC, INC.

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SUITABILITY PETITION

Identification of Petitioner:

This Suitability Petition is submitted on behalf of Phoenix Scientific, Inc., (PSI) 3915 South 48th Street Terrace, St. Joseph, MO 64503 under Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act.

Action Requested:

PSI requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) consisting of a different physical form of the drug product than the approved product. The approved product, Phenylbutazone Tablets, USP 1 gram (NADA 91-818) is a compressed tablet. The proposed generic product will be a granulated powder. The amount of active ingredients administered per dose to the horse will be the same for both products.

The indications for the use of the generic product will be the same as for the approved product. A copy of the approved product labeling is enclosed.

Statement of Grounds:

The proposed product contains the same active ingredient and has the same indications, cautions, and warnings as the approved product. Both products are for oral use in horses. The products will differ only in the physical form of the drug product, a granulated powder for the generic rather than a compressed tablet for the approved product. The label copy will vary only as it relates to the different amount of drug product required to provide the dose. As an example, one (1) tablespoon, standard US measure, of the generic granulated powder may equal one (1) approved Phenylbutazone Tablet, USP 1 gram.

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Environmental Impact:

The action of submitting and reviewing of this Suitability Petition will not normally be expected to have an environmental impact. Therefore, under 21 CFR 25.30(h), we request a categorical exclusion from the requirement to prepare an environmental assessment (EA), since, to the best of our knowledge, no extraordinary circumstances exist.

Economic Impact:

An "Economic Impact" analysis of this action will be provided upon request by the Commissioner.

Certification:

Attached is a statement that Phoenix Scientific, Inc. has included all information known to us, which is unfavorable to this Suitability Petition.

Approval to file an ANADA for this Phenylbutazone Powder based upon this Suitability Petition is requested.

Sincerely:
Phoenix Scientific, Inc.

Robert D. Gunderson
Vice President, Regulatory Affairs

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Certificate of Inclusion of Unfavorable Information

As the Chief Executive Officer for Phoenix Scientific, Inc., I certify that no unfavorable information related to this Suitability Petition has been withheld from the attached Suitability Petition.

February 7, 2000

Kevin M. Schinze
President and CEO
Phoenix Scientific, Inc.
St. Joseph, MO 64503

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AM/BT/AG/BI

PHENYLBUTAZONE TABLETS, USP 1 gram

NADA 91-818, Approved by FDA

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Phenylbutazone chemically is 4-butyl-1, 2 diphenyl-3, 5-pyrazolidinedione.

$C_{19}H_{20}N_2O_2$

Mol. Wt. 308.38

Each tablet contains 1 g of phenylbutazone

BACKGROUND PHARMACOLOGY: Phenylbutazone was first synthesized in 1948 and introduced into human medicine in 1949. Kuzell (1), (2), (3), Payne, (4), Fleming, (5) and Denko, (6) demonstrated the clinical effectiveness of phenylbutazone in gout, gouty arthritis, acute arthritis, acute rheumatism and various other rheumatoid disorders in humans. Fabre (7), Domenjoz, (8), Wilhelmi, (9) and Yourish, (10), have established the anti-rheumatic and anti-inflammatory activity of phenylbutazone. It is entirely unrelated to the steroid hormones.

Toxicity of phenylbutazone has been investigated in rats and mice (11), and dogs (12).

Phenylbutazone has been used by Camberos (13), in thoroughbred horses. Favorable results were reported in cases of traumatism, muscle rupture, strains and inflammations of the third phalanx. Results were not as favorable in the periodic treatment of osteo-arthritis of the stifle and hip, arthrosis of the trapezious muscles and general arthritis. Sutter, (14) reported a favorable response in chronic equine arthritis of long duration, fair results in severely bruised mare and poor results in two cases where the condition was limited to the third phalanx.

INDICATIONS: Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

DOSAGE AND ADMINISTRATION: For Horses Only: Orally 1 to 2 tablets per 500 pounds of body weight, but not to exceed 4 g per animal daily. Use high dose for the first 48 hours, then gradually reduce to a maintenance dose.

CONTRAINDICATIONS: Use with caution in patients who history of drug allergy.

PRECAUTION: In the treatment of inflammatory condit associated with infections, specific anti-infective therapy shoul used concurrently.

WARNING: Not for horses intended for food.

HOW SUPPLIED: Tablets containing 1 gram of phenylbutazone supplied in bottles of 100 tablets.

Store at controlled room temperature, 20° to 25°C (68° to 77°F)

References:

1. Kuzell, WC, Schaffarzick, RW, Naughler, WE, Gandia, C and Mankle, EA: A.M.A. Arch. Inst. Med., 92,646 (1953).
2. Kuzell, WC, Schaffarzick, RW, Brown, B and Mankle, EA: J.A.M.A. 149; 729 (1952).
3. Kuzell, WC, and Schaffarzick, RW: Calif. Med. 77; 319 (1952).
4. Payne, RW, Shelter, MR, Farr, CH, Hellbaum, AA, and Ishmall WK: J. Lab. Clin. Med. 45; 331 (1955).
5. Fleming, J and Will, G: Ann. Rheumat., Dis., 12; 95 (1953).
6. Denko, CW and Rumi, D: American Pract. 6; 1865 (1955).
7. Fabre, J, et al: Semain. Hop. (Paris) 31; 87 (1955).
8. Domenjoz, R, et al: Arzneimittel-Forsch, 5; 488 (1955).
9. Wilhelmi, G and Pulver, R: Arzneimittel-Forsch, 5; 221 (1955).
10. Yourish, W, Paton, B, Brodie, B, Burns, J: A.M.A. Arch. Ophth 53: 264 (1955).
11. Hazelton, LW, Tusing, TW and Hollana, EG: J. Pharmacol, Exp Ther., 109; 387 (1953).
12. Ogilvie, FB and Sutter, MD: Vet. Med 52; 492-4 (1957).
13. Camberos, HR: Rev. Med. Vet. (Buenos Aries) 38: 9 (1956).
14. Sutter, MD: Vet. Med., 53; 83 (Feb. 1958).

801021 Rev. 11

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

SEE PACKAGE INSERT FOR COMPLETE INSTRUCTIONS.

INDICATIONS: Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

DOSAGE AND ADMINISTRATION: For Horses Only: Orally 1 to 2 tablets per 500 pounds of body weight, but not to exceed 4 g per animal daily. Use high dose for the first 48 hours, then gradually reduce to a maintenance dose.

801021 Iss. 6-98

Lot No.

Exp. Date

NDC 59130-715-34

PHENYLBUTAZONE TABLETS, USP 1 gram

ANTI-INFLAMMATORY

For Oral Use In Horses Only

KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NET CONTENTS: 100 TABLETS

NADA 91-818, Approved by FDA

AmTech® Group, Inc

Each tablet contains:

Phenylbutazone . . . . . 1 gram

Dispense in tight, child resistant containers.

WARNING: Not for use in horses intended for food.

Store at controlled room temperature, 20° to 25°C (68° to 77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

CERTIFIED

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MAIL

★ ★ ★ UNITED STATES POSTAGE

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2413 $03.64⁰ PB8539488 FEB 07 00
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